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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/775,767

02/10/2004

Andrew H. Fischer

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

02/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/775,767	Applicant(s) FISCHER, ANDREW H.	
	Examiner WILLIAM H. BEISNER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12, 15-18 and 26-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12, 15-18 and 26-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/5/07 and 12/7/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/697,993, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

It is noted that that originally filed instant claims 4 and 5 are not supported by the written description of parent application 10/697,993.

Information Disclosure Statement

2. The information disclosure statements filed 11/5/2007 and 12/7/2007 have been considered and made of record.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the

Art Unit: 1797

following is required: The specification fails to provide antecedent basis for the language and/or limitations of original claims 4 and 5.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16, 17 and 26-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims are considered new matter for the following reasons:

i) The amendment filed 11/23/2007 includes numerous amendments to the claims and additionally includes 69 new claims. Applicant's remarks dated 11/23/2007 merely state the following: *Claims 1-25 were previously pending in this application. By this response, Applicant amends claims 1, 6-8, 10, 12, and 15-18, cancels claims 9, 13, 14, and 19-25, and adds new claims 26-94. As a result, claims 1-8, 10, 12, 15-18, and 26-94 are pending for examination with claims 1, 38, 53, and 79 being independent claims. No new matter is added.*

It is noted that Applicant's remarks dated 11/23/2007 has not pointed out where the limitations are supported and they are not readily apparent to the examiner. As a result, the claim amendments and new claims are considered new matter (See MPEP 2163.04 (I)(B)).

ii) Any of the amended claims and/or new claims that include limitations drawn to a pipette is also considered new matter since support for this limitation is not apparent to the Examiner. Again, it is noted that Applicant has not pointed to a portion of the specification that provides support for this new claim language.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-8, 10-12, 15-18 and 26-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick (US 4,569,647) in view of Williamson, IV et al.(US 5,817,032).

The reference of McCormick discloses a flow through method for forming an embedded cell block that includes providing a cell sample to a filter device (10); flowing a first reagent through the captured portion of the cell sample and filter to dehydrate the cell sample (See column 6, lines 1-60); flowing a second reagent through the captured portion of the cell sample and filter to remove the first reagent (See column 6, line 61, to column 7, line 8); and flowing an embedding solution through the captured portion of the cell sample and filter (See column 7, lines 9-22).

Claim 1 differs by requiring that the cell sample is automatically delivered to the filter device.

The reference of Williamson, IV et al. discloses that it is known in the art of tissue processing to automate the entire process, including adding the cell sample to the filter device, such that the sample does not have to be manually handled (See column 8, lines 45-60; and column 14, lines 28-67).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to automate the addition of the cell sample to the filter device of the primary reference for the known and expected result of automating a manual process and reducing the need to manually handle the cell sample.

With respect to claim 2, the first reagent is alcohol (See column 6, line 2).

With respect to claims 3 and 4, the second reagent is xylene (See column 7, line 1) and would inherently have the claimed triple point.

With respect to claims 5 and 43, the second reagent is allowed to evaporate prior to flowing the embedding solution (See column 7, lines 9-12).

Art Unit: 1797

With respect to claim 6, the embedding solution is paraffin (See column 7, line 12).

With respect to claims 7 and 8, the sample can be stained prior to embedding (See column 1, lines 16-21).

With respect to claims 10 and 11, formalin is also flowed through the captured portion of the cell sample and filter (See column 5, lines 49-68).

With respect to claim 12, it would have been obvious to one of ordinary skill in the art to provide additional well known preparatory steps, such as decalcification, to the sample as is conventional in the art.

With respect to claim 15, the reference of McCormick discloses the use of a vacuum device (138). Whether or not it is used during the processing steps would have been clearly within the purview of one having ordinary skill in the art.

With respect to claims 16, 17 and 39-42, the use of other fluid delivery structures, such as pipettes, would have been obvious to one of ordinary skill in the art while providing an art recognized means for adding reagents to a reaction vessel.

With respect to claim 18, the reference of McCormick discloses the use of pumps (102). Whether or not it is used during the processing steps would have been clearly within the purview of one having ordinary skill in the art.

With respect to claims 26-28, 30, 31 and 44-47, controlling the temperature of the final sample block would have been well within the purview of one having ordinary skill in the art for removing the block from the mold for further processing.

With respect to claim 29, the reference of McCormick discloses the use of a spacer (86).

With respect to claims 32-37 and 48-52, when automating the operation of the device as is done in the modified primary reference, it would have been obvious to one of ordinary skill in the art to determine the optimum manner in which to monitor and/or control the flow of the reagent through the system while maintaining the efficiency of the process.

With respect to claim 38, the reference of Williamson, IV et al. discloses the use of a support (413) when automatically adding the sample to the filter device (See Figure 8).

9. Claims 53-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick (US 4,569,647) in view of Williamson, IV et al.(US 5,817,032) taken further in view of Louder et al.(US 4,141,312).

The combination of the references of McCormick and Williamson, IV et al. has been discussed above.

Claim 53 differs by reciting that the embedding solution is heated about the captured portion of the cell sample.

The reference of Louder et al. discloses that it is conventional in the art to provide a heater (24) so as to heat the embedding solution about the captured portion of a cell sample held within filter device (10) (See column 8, lines 30-39).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to heat the embedding solution about the captured portion of the cell sample for the known and expected result of ensuring efficient contact between the embedding solution and the cell sample.

Art Unit: 1797

With respect to claims 54, 55, 80 and 81, it would have been obvious to one of ordinary skill in the art to optimize the design of the system so as to ensure optimal heat exchange between the filter device and heater/cooler system.

With respect to claim 56, controlling the temperature of the final sample block would have been well within the purview of one having ordinary skill in the art for removing the block from the mold for further processing.

With respect to claim 57, the first reagent is alcohol (See column 6, line 2).

With respect to claim 58, the second reagent is xylene (See column 7, line 1).

With respect to claims 59 and 85, the second reagent is allowed to evaporate prior to flowing the embedding solution (See column 7, lines 9-12).

With respect to claim 60, the embedding solution is paraffin (See column 7, line 12).

With respect to claims 61 and 62, the sample can be stained prior to embedding (See column 1, lines 16-21).

With respect to claims 63 and 64, formalin is also flowed through the captured portion of the cell sample and filter (See column 5, lines 49-68).

With respect to claim 65, it would have been obvious to one of ordinary skill in the art to provide additional well known preparatory steps, such as decalcification, to the sample as is conventional in the art.

With respect to claim 66, the reference of McCormick discloses the use of a vacuum device (138). Whether or not it is used during the processing steps would have been clearly within the purview of one having ordinary skill in the art.

Art Unit: 1797

With respect to claims 67 and 82-84, the use of other fluid delivery structures, such as pipettes, would have been obvious to one of ordinary skill in the art while providing an art recognized means for adding reagents to a reaction vessel.

With respect to claim 68, the reference of McCormick discloses the use of pumps (102). Whether or not it is used during the processing steps would have been clearly within the purview of one having ordinary skill in the art.

With respect to claims 69 and 86, when the embedded sample is removed from the filter, a surface of the block would be exposed.

With respect to claims 70, 71, and 87, controlling the temperature of the final sample block would have been well within the purview of one having ordinary skill in the art for removing the block from the mold for further processing.

With respect to claim 72, the reference of McCormick discloses the use of a spacer (86).

With respect to claims 73-78 and 88-92, when automating the operation of the device as is done in the modified primary reference, it would have been obvious to one of ordinary skill in the art to determine the optimum manner in which to monitor and/or control the flow of the reagent through the system while maintaining the efficiency of the process.

With respect to claim 79, the reference of Williamson, IV et al. discloses the use of a support (413) when automatically adding the sample to the filter device (See Figure 8).

With respect to claims 93 and 94, the cell sample is automatically added to the filter device as discussed in the combination of the references of McCormick and Williamson, IV et al.

Double Patenting

Art Unit: 1797

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-8, 10-12, 15-18 and 26-94 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,913,921 in view of McCormick (US 4,569,647) and Williamson, IV et al.(US 5,817,032) alone or taken further in view of Louder et al.(US 4,141,312).

Claims 1-18 of US Patent No. 6,913,921 encompass a device for embedding cell samples.

The claims differ by failing to recite method steps of using the recited device.

The references of McCormick and Williamson both disclose automated methods for automating a cell sample embedding process.

The reference of Louder et al. discloses the use of a heater with an embedding container for holding a cell sample filter device.

In view of this teachings, it would have been obvious to one of ordinary skill in the art to employ the device of the patented claims for performing cell embedding methods as suggested

Art Unit: 1797

by the references of McCormick and Williamson alone or further in view of Louder et al.(See the prior art rejections above regarding the detailed disclosures of the references of McCormick, Williamson and Louder et al).

Response to Arguments

12. Applicant's arguments, see pages 15-16, filed 11/23/2007, with respect to the rejection(s) of claim(s) 1-25 under 35 USC 103 and obviousness-type double patenting have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of McCormick (US 4,569,647) and Williamson, IV et al.(US 5,817,032) alone or taken further in view of Louder et al.(US 4,141,312). .

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1797

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1797**

WHB